September 2010

[KX 825] **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

(Regulations 2008 - 2009)

(Candidates admitted from 2008-2009 onwards)

FIFTH YEAR

Paper I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 marks**

Answer All questions

I. Essay Questions : **(2 x 20 = 40)**

1. Define Clinical Trials? Discuss in detail five various phases involved in drug development process.
2. Discuss the composition, responsibilities and procedures of IRB/IEC.

II. Write Short Notes : **(6 x 5 = 30)**

1. Significance of post marketing surveillance.
2. Roles and responsibilities of Investigations.
3. Study designs in a clinical trail.
4. Informed consent process.
5. ICH guidelines in clinical trials.
6. Purposes of an audit in a clinical trial.

****

October 2011

[KZ 825] **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : 3 hours **Maximum : 100 marks**
(180 Min)

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. (a) Define investigational new drug application and describes the component and categories of investigational new drug application	17	40 min.	20
(b) What are the essential documents for the conducting of clinical trials and its purpose?			
2. (a) Roles and responsibilities of auditors in clinical research			
(b) Define serious adverse event in clinical trial and responsibilities of investigators in reporting	17	40 min.	20
II. Write notes on :			
1. Various phases of clinical trial	4	10 min.	6
2. Informed consent process	4	10 min.	6
3. Central drug standard control organisation and food and drug administration	4	10 min.	6
4. Investigators brochure	4	10 min.	6
5. Randomization	4	10 min.	6
6. Source documents in clinical trial	4	10 min.	6
7. Vulnerable subjects	4	10 min.	6
8. Roles and responsibilities of regulatory authority in relation to clinical trial	4	10 min.	6
9. What are the responsibilities of clinical data manager?	4	10 min.	6
10. Define the followings: (i). Blinding (ii). Comparator (iii). Good clinical practice.	4	10 min.	6

****

[LD 825] **OCTOBER 2013** **Sub. Code: 3825**

PHARM.D / POST BACCALAUREATE DEGREE EXAMINATIONS

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time: Three Hours **Maximum: 70 marks**

Answer ALL questions in the same order

I. Elaborate on: **(2 x 20 = 40)**

1. What is ANDA?
   What are the drugs come under ANDA?
   What is meant by generic drugs?
   Write a note on post marketing surveillance.

2. What is Institutional human ethical committee?
   Give the composition, qualification required for the members.
   Explain the functions of the committee.

II. Write notes on: **(10 x 3 = 30)**

1. Explain the importance of Pharmacological information in drug discovery.
2. Name various chemical characteristics of the drug.
3. Write a not on GCP.
4. What are the challenges faced by the investigator in clinical trials.
5. Write a not on schedule Y.
6. Explain the responsibility of the auditors in clinical trials.
7. Explain the protocol involved in data management in clinical research.
8. Differentiate Phase II & Phase III clinical trials.
9. Why randomization is important in clinical research?
10. Write the significance of preclinical testing in clinical research.

****

[LE 825] **APRIL 2014** **Sub. Code: 3825**

PHARM. D/POST BACCALAUREATE DEGREE EXAMS
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : 3 hours **Maximum : 70 marks**

I. Elaborate on : **(2x20=40)**

1. a) What is clinical research and why do we need to conduct research?
   b) What are the different stages of drug development process?

2. a) Roles and responsibilities of contract research organizations in clinical research.
   b) Define Investigator's brochure and describes about its components.

II. Write notes on : **(10x3=30)**

1. Good clinical practice and its principles
2. Informed consent process
3. Central drug standard control organisation and food and drug administration
4. Various ethical guidelines in clinical research
5. Safety monitoring in clinical trials
6. Source documents in clinical trial
7. Vulnerable subjects
8. Roles and responsibilities of Investigator in clinical trial
9. What are the responsibilities of regulatory authority in clinical research?
10. Define the followings:
    a) Case report form (CRF)
    b) Impartial witness
    c) Schedule- Y

****